IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

HOLOGIC, INC. AND CYTYC SURGICAL PRODUCTS, LLC,	)	
Plaintiffs,	)	
v.	)	Civ. No. 15-1031-SLR
MINERVA SURGICAL, INC.,	)	
Defendant.	)	

MEMORANDUM ORDER

At Wilmington this 2nd day of June, 2016, having reviewed the papers filed in connection with plaintiffs' motion for preliminary injunction, and having heard oral argument on same;

IT IS ORDERED that plaintiffs' motion (D.I. 9) is denied, for the reasons that follow:

1. **Procedural background.** On November 6, 2015, plaintiffs Hologic, Inc. and Cytyc Surgical Products, LLC ("Cytyc") (collectively plaintiffs or "Hologic") filed a complaint alleging infringement of U.S. Patent Nos. 6,872,183 ("the '183 patent"),[1] 8,998,898 ("the '898 patent"),[2] and 9,095,348 ("the '348 patent"),[3] against defendant

[1] Titled "System and Method for Detecting Perforations in a Body Cavity," filed May 24, 2004 and issued March 29, 2005.
[2] Titled "Moisture Transport System for Contact Electrocoagulation," filed May 15, 2014 and issued April 7, 2015.
[3] Titled "Moisture Transport System for Contact Electrocoagulation," filed August 8, 2013 and issued August 4, 2015.

Minerva Surgical Inc. ("Minerva").[4] (D.I. 1) On February 5, 2016, Hologic filed a second amended complaint pursuant to a stipulation, adding allegations relating to U.S. Patent No. 9,247,989 ("the '989 patent").[5, 6] (D.I. 69, 70) On February 29, 2016, the court denied Minerva's motion to transfer and strike Hologic's preliminary injunction motion.[7] (D.I. 82) On March 4, 2016, Minerva answered the complaint and counterclaimed. (D.I. 83) On March 28, 2016, Hologic answered the counterclaims. (D.I. 106)

2. Hologic, Inc. is a corporation organized and existing under the laws of the State of Delaware with a principal place of business in Marlborough, Massachusetts. It provides women's health care services including diagnostics, screening, and imaging, as well as medical intervention and treatment. Cytyc is a limited liability company organized and existing under the laws of the Commonwealth of Massachusetts with a principal place of business in Marlborough, Massachusetts. Cytyc is engaged in designing, developing, and selling medical devices for the treatment of excessive or abnormal endometrial bleeding. Cytyc is a wholly-owned subsidiary of Hologic, Inc. (D.I. 70 at ¶¶ 2-4) Minerva is a corporation formed in 2008. It is organized and existing under the laws of the State of Delaware with a principal place of business in Redwood City, California. Minerva has developed and brought to market a new technology for the treatment of abnormal uterine bleeding. (D.I. 83 at ¶¶ 119, 124)

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[4] On January 6, 2016, Minerva filed a motion to dismiss, which was subsequently withdrawn. (D.I. 43, 62) On January 25, 2016, Hologic filed an amended complaint. (D.I. 59)

[5] Titled "Moisture Transport System for Contact Electrocoagulation," filed March 2, 2015 and issued February 2, 2016.

[6] For purposes of the preliminary injunction motion practice, the parties agreed not to rely on the '898 patent. (D.I. 42 at 2) Neither party refers to the '989 patent. (D.I. 11, 86)

[7] The court has jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

3. **Factual background.** "Menorrhagia" is abnormally heavy menstrual bleeding in amount or duration. One treatment for this condition is an "endometrial ablation," wherein lining of the uterus is destroyed. In the early 1990s, physicians had to visually inspect the uterus for perforations using a hysteroscope, as such perforations can allow steam or hot fluids generated during ablation to escape the uterus and cause serious injury to nearby organs. Furthermore, small perforations were hard to detect. To perform the ablation, physicians used instruments such as an electrified metal ball or wire loop to burn tissue away inside the uterus. The procedures were lengthy and carried serious risks. (D.I. 11 at 2-3)

4. NovaCept Corporation ("NovaCept") under the direction of Csaba Truckai ("Truckai") and his design team developed the NovaSure system ("NovaSure") in the late-1990s. The U.S. Food and Drug Administration ("FDA") approved NovaSure in 2001. (D.I. 70 at ¶ 10; D.I. 86 at 2) In May 2004, Cytyc Corporation, a leading provider of diagnostic and therapeutic treatments for women, acquired NovaCept for $325 million. In 2007, Hologic, Inc. acquired Cytyc Corporation. (D.I. 11 at 5; D.I. 86 at 2)

5. Prior to an ablation procedure, NovaSure uses computerized monitoring to detect perforations in the uterus, by applying CO_2 gas to the uterus and measuring whether there is any flow of gas out of the uterus. NovaSure employs an application head with a triangular shape designed to conform to the shape of the uterus, which ablates the endometrial lining throughout the cavity in two minutes or less. The procedure is considerably shorter, less expensive, and more convenient for the patient. NovaSure also provides a "moisture transport" function with a vacuum used to remove steam and moisture from the cavity during energy delivery. (D.I. 11 at 3-5)

6. In July 2015, Minerva obtained FDA approval for a new device for the treatment of menorrhagia ("Minerva EAS"), developed by Truckai and his design team. Minerva has hired and trained a sales force to begin selling Minerva EAS to physicians. (D.I. 86 at 4)

7. **Standard.** "The decision to grant or deny . . . injunctive relief is an act of equitable discretion by the district court." *eBay, Inc. v. MercExchange, LLC*, 547 U.S. 388, 391 (2006); *Abbott Labs. v. Andrx Pharm., Inc.*, 452 F.3d 1331, 1334 (Fed. Cir. 2006). The grant of such relief is considered an "extraordinary remedy" that should be granted only in "limited circumstances." *See Kos Pharma., Inc. v. Andrx Corp.*, 369 F.3d 700, 708 (3d Cir. 2004) (citation omitted). A party seeking preliminary injunction relief must demonstrate: (1) a reasonable likelihood of success on the merits; (2) the prospect of irreparable harm in the absence of an injunction; (3) that this harm would exceed harm to the opposing party; and (4) the public interest favors such relief. *See, e.g., Sciele Pharma Inc. v. Lupin Ltd.*, 684 F.3d 1253, 1259 (Fed. Cir. 2012); *Abbott Labs v. Sandoz, Inc.*, 544 F.3d 1341, 1344 (Fed. Cir. 2008). "If either or both of the fundamental requirements—likelihood of success on the merits and probability of irreparable harm if relief is not granted—are absent, an injunction cannot issue." *Antares Pharma., Inc. v. Medac Pharma., Inc.*, 55 F. Supp. 3d 526, 529 (D. Del. 2014) (citing *McKeesport Hosp. v. Accreditation Council for Graduate Med. Educ.*, 24 F.3d 519, 523 (3d Cir. 1994)).

8. At the preliminary injunction stage of a case, the movant "'must demonstrate that . . . at least one of [the] allegedly infringed claims will . . . likely withstand the validity

challenges presented by the accused infringer.'" *Abbott Labs.*, 452 F.3d at 1335 (citation omitted).

> As to the burden regarding invalidity allegations, "[v]alidity challenges during preliminary injunction proceedings can be successful, that is, they may raise substantial questions of invalidity, on evidence that would not suffice to support a judgment of invalidity at trial." . . . In resisting a preliminary injunction, however, one need not make out a case of actual invalidity. Vulnerability is the issue at the preliminary injunction stage, while validity is the issue at trial. The showing of a substantial question as to invalidity thus requires less proof than the clear and convincing showing necessary to establish invalidity at trial.

Id. (citation omitted).

9. Even if a movant demonstrates a likelihood of success on the merits, there is no presumption of irreparable harm. *See, e.g., eBay*, 547 U.S. at 393. To establish irreparable harm, the movant must "clearly establish[ ] that monetary damages could not suffice." *Id.* at 1348. Moreover, Federal Circuit precedent requires a showing of some causal nexus between the alleged infringement and the alleged harm. *See Apple, Inc. v. Samsung Elecs. Co.*, 678 F.3d 1314, 1324 (Fed. Cir. 2012) ("Sales lost to an infringing product cannot irreparably harm a patentee if consumers buy that product for reasons other than the patented feature.").

10. **The '348 patent.** The '348 patent is directed to "an apparatus and method of ablating and/or coagulating tissue, such as that of the uterus or other organ." It uses "an electrode array," which "includes a fluid permeable elastic member preferably formed of a metallized fabric having insulating regions and conductive regions thereon." To use the apparatus, "the electrode array is positioned in contact with tissue to be ablated, ablation energy is delivered through the array to the tissue to cause the tissue to dehydrate, and moisture generated during dehydration is actively or passively drawn

into the array and away from the tissue." ('348 patent, 2:34-45) The specification describes two exemplary embodiments. The first embodiment describes an ablation device comprised generally of three major components – RF applicator head, main body, and handle. (*Id.* at 4:55-58) The applicator head includes an array of electrodes formed on the surface of an electrode carrying means. (*Id.* at 4:58-61) "The second embodiment differs from the first embodiment primarily in its electrode pattern and in the mechanism used to deploy the electrode applicator head or array." Aspects of the two "exemplary embodiments and their methods of operation may be combined without departing from the scope of the present invention." (*Id.* at 11:50-58) Claim 1 recites:

> A device for treating a uterus comprising:
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> an elongate member having a proximal portion and a distal portion, the elongate member comprising an outer sleeve and an inner sleeve slidably and coaxially disposed within the outer sleeve;
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> an **applicator head** coupled to the distal portion, the applicator head defining an interior volume and having a contracted state and an expanded state, the contracted state being configured for transcervical insertion and the expanded state being configured to conform to the shape of the uterus, the applicator head including one or more electrodes for ablating endometrial lining tissue of the uterus;
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> a handle coupled to the proximal portion of the elongate member, wherein the handle comprises a frame, a proximal grip and a distal grip pivotally attached to one another at a pivot point and operably coupled to the applicator head so that when the proximal grip and the distal grip are moved closer together, the applicator head transitions from the contracted state to the expanded state;
>
> a **deflecting mechanism** including flexures disposed within the applicator head, the flexures including first and second internal flexures and first and second external flexures, the first and second external flexures being coupled to the outer sleeve and the first and second internal flexures being coupled to the inner sleeve, wherein the deflecting mechanism is configured so that translating the inner sleeve relative to the frame causes the applicator head to transition from the contracted state to the expanded state; and

> an **indicator mechanism** operably coupled to the inner sleeve, the indicator mechanism configured to indicate a dimension of the uterus.

(*Id.* at 19:9-42) (emphasis added)

11. **Likelihood of success on the merits – infringement.** As to claim 1, Minerva argues that Minerva EAS lacks the claimed "deflecting mechanism," "applicator head," and "indicator mechanism." (D.I. 86 at 14, 16, 18) For each of these limitations, Hologic asserts that the claim language is clear and readily understood, therefore, expert testimony or extrinsic evidence is unnecessary for claim construction. (D.I. 11 at 9) Minerva offers specific constructions for the disputed limitations, which the court discusses below.

12. **"Deflecting mechanism."** In the description of the second embodiment, the '348 specification explains that the "[a]pplicator head 102 includes an external electrode array 102a and an internal deflecting mechanism 102b used to expand and tension the array for positioning into contact with the tissue." ('348 patent, 12:5-8) The "[d]eflecting mechanism 102b and its deployment structure is enclosed within electrode array 102a." (*Id.* at 13:8-9) The deflecting mechanism is preferably configured such that the distal tips of the flexures 124 are sufficiently flexible to prevent tissue puncture during deployment and/or use." (*Id.* at 14:1-3) "The deflecting mechanism formed by the flexures 124, 136, and [transverse] ribbon 138 forms the array into the substantially triangular shape shown in [figure] 23, which is particularly adaptable to most uterine shapes." (*Id.* at 14:21-24) The specification further explains that "[e]ach internal flexure 136 is connected at its distal end to one of the flexures 124 and a transverse ribbon 138 extends between the distal portions of the internal flexures 136." The transverse ribbon

"is preferably pre-shaped such that when in the relaxed condition the ribbon assumes the corrugated configuration shown in [figure] 23 and such that when in a compressed condition it is folded along the plurality of creases 140 that extend along its length." (*Id.* at 13:60-54) Dependent claim 2 recites "[t]he device of claim 1 further comprising a transverse ribbon coupled to a distal end of the first and second external flexures, wherein the transverse ribbon is in a relaxed condition when the applicator head is in the expanded state." (*Id.* at 19:43-46)

13. Hologic identifies the flexures in the applicator head of Minerva EAS as satisfying the "deflecting mechanism" limitation. (D.I. 11 at 11) Minerva's proposed construction[8] is repetitive in the context of the actual claim language, which recites and describes "flexures." Minerva's non-infringement argument relies on this construction, i.e., that Minerva EAS does not use or need a transverse ribbon to conform to the shape of the uterus. (D.I. 86 at 16) Neither claim 1 nor the specification requires that the transverse ribbon be part of the "deflecting mechanism." Given the language of the specification and claims, Hologic has made a prima facia showing that Minerva EAS satisfies this limitation.

14. **"Applicator head."** The summary of the invention explains that the "electrode array includes a fluid permeable elastic member preferably formed of a metallized fabric having insulating regions and conductive regions thereon . . . and moisture generated during dehydration is actively or passively drawn into the array and away from the tissue." ('348 patent, 2:37-45) In the first embodiment, the applicator

[8] "A deployment structure enclosed within the electrode array of the applicator head that consists of outer flexures, inner flexures and a transverse ribbon that extends between the flexures." (D.I. 86 at 14)

head "includes an electrode carrying means 12 mounted to the distal end of the shaft 10 and an array of electrodes 14 formed on the surface of the electrode carrying means 12." (*Id.* at 4:58-61) The electrode carrying means is "preferably a sack formed of a material which is non-conductive, which is permeable to moisture and/or which has a tendency to absorb moisture. . . . Alternatively, the electrode carrying means may be formed of a metallized fabric." (*Id.* at 5:52-61) The main body of the ablation device includes a shaft with a "suction/insufflation tube" extending through it. (*Id.* at 4:57, 5:3-4) The suction/insufflation tube is "coupled to the flow pathway so that gas fluid may be introduced into, or withdrawn from the suction/insufflation tube 17 via the suction/insufflation port 38. For example, suction may be applied to the fluid port 38 using a suction/insufflation unit 40." (*Id.* at 8:20-25) The water vapor from the uterine cavity passes "thorough the permeable electrode carrying means 12, into the suction/insufflation tube 17 via holes 17a, through the tube 17, and through the suction/insufflation unit 40 via the port 38." (*Id.* at 8:27-29) The specification also describes the operation of the ablation device, including that "[m]oisture removal from the ablation site may be further facilitated by the application of suction to the shaft 10 using the suction/insufflation unit 40." (*Id.* at 10:65-67) The specification explains that "liquid build-up at the ablation site is detrimental" and that moisture is shunted away from the ablation site, which prevents liquid build-up. (*Id.* at 11:1-13) Suction may also be used to help draw the organ tissue towards the electrode carrying means and into better contact with the electrodes. (*Id.* at 9:1-6) The specification provides that "additional components inside" the electrode carrying means may "add structural integrity to [it] when it is deployed within the body." For example, "a pair of inflatable

balloons may be arranged inside the electrode carrying means," which balloons can then be inflated after insertion of the apparatus into the organ. (*Id.* at 8:47-67)

15. In the second embodiment, the applicator head "includes an external electrode array 102a and an internal deflecting mechanism 102b used to expand and tension the array for positioning into contact with the tissue." (*Id.* at 12:5-8) The array "is formed of a stretchable metallized fabric mesh which is preferably knitted from a nylon and spandex knit plated with gold or other conductive material." (*Id.* at 12:10-12) The embodiment describes using a vacuum source, which causes "application of suction" to help "draw uterine tissue into contact with the array." (*Id.* at 18:40-43) The embodiment describes a "plurality of longitudinally spaced apertures" formed in each flexure that allow moisture to pass through the flexures and be drawn into a hypotube 120 using a vacuum source. (*Id.* at 13:13-18) In describing the operation of the second embodiment, the specification explains that as moisture is released from the tissue, the vacuum source helps to draw moisture from the uterine cavity into the hypotube. (*Id.* at 18:44-52)

16. Hologic identifies Minerva EAS' applicator head as meeting this limitation. Minerva argues that Minerva EAS "uses a fluid-tight, sealed silicone outer membrane, which is not permeable to moisture;" instead, the formation of a moisture layer is beneficial to the operation of Minerva EAS. (D.I. 86 at 17) Minerva's proposed construction[9] seeks to narrow the claim language to the second embodiment and adds limitations which are not required by the specification or claim language. Specifically,

[9] "A working end having a permeable external electrode array into which moisture is drawn using suction." (D.I. 86 at 16)

the use of suction to draw in moisture is not required. As to permeability, the specification contemplates that the electrode array be made of a material that is permeable to moisture. Hologic's reference to the balloon example in the first embodiment is not helpful, as the context of that example is to provide stability to the electrode carrying means.[10] Minerva has raised a substantial question regarding whether Minerva EAS satisfies this limitation.

17. **"Indicator mechanism."** In the second exemplary embodiment, the specification describes a "measurement device," "for easily measuring the uterine width and for displaying the measured width on a gauge." A dial face "includes calibration markings corresponding to an appropriate range of uterine widths." The uterine width is

> preferably input into an RF generator system and used by the system to calculate an appropriate ablation power . . . . Alternately, the width as measured by the apparatus of the invention . . . may be used by the user to calculate the power to be supplied to the array to achieve the desired ablation depth.

('348 patent, 14:32-67)

18. Hologic identifies Minerva EAS' red and green areas and the lines of 3, 4, and 5 dots as meeting the "indicator mechanism" limitation. (D.I. 11 at 11) Minerva

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[10] The specification describes the shortcomings of the prior art methods including that "water drawn from the tissue creates a path of conductivity through which current traveling through the electrodes will flow" and "the heated liquid around the electrodes causes thermal ablation to continue well beyond the desired ablation depths." ('348 patent, 2:9-19) The specification also states that "liquid build-up at the ablation site is detrimental." (*Id.* at 11:1-13) The court concludes that such disclosures do not rise to the level of disclaimer, sufficient to narrow the disputed claim limitation as desired by Minerva. *Cf. Pacing Techs., LLC v. Garmin Int'l, Inc.*, 778 F.3d 1021, 1025 (Fed. Cir. 2015) (citing *Inpro II Licensing, S.A.R.L. v. T–Mobile USA Inc.*, 450 F.3d 1350, 1354-55 (Fed. Cir. 2006)) ("Likewise, we have used disclaimer to limit a claim element to a feature of the preferred embodiment when the specification described that feature as a 'very important feature . . . in an aspect of the present invention,' and disparaged alternatives to that feature.").

EAS' manufacturing specification refers to the indicator on the handpiece as a "width indicator." (D.I. 115, ex. 10 at 6.2.12, 6.3.13) The dot scale on the width indicator shows widths of about 3, 4, and 5 cm, respectively, via the rows of 3, 4, and 5 dots. (D.I. 115, ex. 8 at 42412; ex.10 at 6.3.13) Minerva's medical director testified that Minerva's clinical data excludes women with uteri that are smaller than 2.5 cm and the width indicator on Minerva EAS' handpiece indicates when a patient's uterus is smaller than 2.5 cm. (D.I. 115, ex. 7 at 164:22-165:5) Minerva's proposed construction limiting "indicator mechanism" to "a mechanism configured to indicate a measurement of width in units" is incorrect. (D.I. 86 at 18-19) Hologic has made a prima facia showing that Minerva EAS satisfies this limitation.

19. **Likelihood of success on the merits – invalidity.** Minerva argues that there is no enabling disclosure for a plasma formation array with a non-permeable and fluid-tight silicone membrane. Minerva's expert opines that it would require undue experimentation for a person of ordinary skill in the art to arrive at Minerva EAS' design, particularly as the specification teaches away from the thermal techniques used by Minerva EAS. (D.I. 88 at ¶¶ 175-76) Hologic argues that Minerva's claim construction is incorrect and that the specification describes non-permeable arrays in figure 20. (D.I. 114 at 8-9) As discussed above regarding the construction of "applicator head," the specification contemplates membrane permeability. Minerva has raised a substantial question of invalidity.[11]

[11] Minerva points out that it has filed an IPR petition challenging the validity of the '348 patent and asserted a defense based on obviousness-type double-patenting to establish that the correct expiration date for the '348 patent is April 12, 2016. (D.I. 86 at 20) Such assertions carry little weight in the present analysis.

20. **The '183 patent.** The '183 patent is directed to "a system and method for detecting perforations in a body cavity." The system delivers a fluid (either liquid or gas) "into a body cavity to slightly pressurize the cavity. A pressure sensing system monitors the pressure within the cavity for a predetermined test period. If cavity pressure is not substantially sustained during the test period, the physician is alerted." In the preferred form of the system, the perforation detection functionality is provided with an RF ablation system. ('183 patent, 1:49-62) Claim 9 recites:

> A method of detecting a perforation in a uterus, comprising the steps of:
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> passing an inflation medium into the uterus;
>
> monitoring for the presence of a perforation in the uterus using a **pressure sensor**;
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> if no perforation is detected during the monitoring step, permitting ablation of the uterus using an ablation device; and
>
> if a perforation is detected during the monitoring step, preventing ablation of the uterus.

(*Id.* at 8:39-48) (emphasis added) Dependent claim 13 limits claim 9 reciting, "wherein the inflation medium is introduced using the ablation device." (*Id.* at 60-61)

21. **"Pressure sensor."** The specification explains that "a pressure sensing system" is "fluidly coupled to the medical device via [a] pressure detection/signal line" and used to monitor the pressure within the body cavity. Fluid or gas is delivered to the body cavity and the pressure sensing system detects "whether elevated pressure can be maintained above a predetermined threshold level over a predetermined period of time. If it cannot, the user is alerted that there may be a perforation in the organ." ('183 patent, 2:36-44) The pressure sensor "monitors pressure in the pressure signal line . . . and delivers the signal to the microprocessor." (*Id.* at 5:23-25) The specification

explains that during testing "[w]hen the pressure at gauge 84 rises and remains above 50 mmHg for 4 seconds, the test has passed." (*Id.* at 6:44-46)

22. Hologic has identified Minerva EAS' flow meter as meeting the "pressure sensor" limitation. Minerva argues that the flow meter does not measure pressure (differential or otherwise) to operate and its output is not a pressure measurement.[12] (D.I. 86 at 8-11) Minerva EAS' operator manual describes a "uterine integrity test" aimed at detecting perforations. (D.I. 12, ex. 11 at 9, 33) Minerva's expert, Dr. Tucker, testified, "[a]s the pressure goes down, the flow rate goes up. As the pressure goes up, the flow rate goes down." (D.I. 115, ex. 2 at 64:17-20) The design documents for Minerva EAS state that "if the uterine cavity and the system is perforation free, gas used to insufflate the uterine cavity will stop flowing once the gas pressure in the uterine cavity matches the supply pressure." (D.I. 87, ex. 82 at 2337) The court concludes that the evidence supports a prima facia showing of infringement.[13, 14]

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[12] Minerva criticizes William Churchill's ("Churchill") analysis under the doctrine of equivalents, arguing that Churchill's chart is conclusory and only analyzes a hypothetical "standard flow meter." Minerva's expert, Dr. Tucker, testified that Minerva EAS uses a "standard flow meter." (D.I. 115, ex. 2 at 33:20-25)

[13] Minerva's argument that Minerva EAS embodies Minerva's patent (U.S. Patent No. 8,343,078) and uses a flow meter is relevant but not dispositive of the issue at bar. *National Presto Indus., Inc. v. West Bend Co.*, 76 F.3d 1185, 1192 (Fed. Cir. 1996) ("The fact of separate patentability is relevant and entitled to due weight.").

[14] The court declines to analyze Minerva's prosecution history estoppel argument at length. (D.I. 86 at 12-13) During the prosecution history of a related application, the PTO rejected a claim with the limitation "monitoring a pressure within the body cavity for a predetermined amount of time," because the prior art disclosed "a system and method for . . . monitoring pressure within the body cavity for a predetermined amount of time." The claim was ultimately allowed after amending other elements of the claim to overcome the rejection. In the application which issued as the '183 patent, the patentee included a claim with the same limitation. Such claim was then cancelled and a new claim was added reciting "monitoring for the presence of a perforation in the uterus using a pressure sensor." Contrary to Minerva's argument, the court discerns no clear and unmistakable surrender of all equivalents to a "pressure sensor." Cf. *Festo Corp. v.*

23. **Likelihood of success on the merits – invalidity.** Dr. Tucker opines that a person of ordinary skill would need to engage in undue experimentation to use a flow meter to perform the claimed "monitoring" function. Therefore, Minerva argues that the disclosure lacks enablement. (D.I. 88 at ¶¶ 116-19) Hologic disputes this conclusion, arguing that Dr. Tucker agreed that a person of ordinary skill could measure flow rate and pressure. (D.I. 115, ex. 2 at 64:24-66:2; ex. 6) According to Hologic, known methods may be used to quantify the relationship between flow and pressure in the uterus. (D.I. 114 at 5) Based on the evidence presented by the parties, the court concludes that Minerva has not raised a substantial question of invalidity in this regard.

24. **Likelihood – conclusion.** As to the '348 patent, Minerva has advanced plausible non-infringement and invalidity arguments with respect to the "applicator head" limitation. As to the '183 patent, Hologic has put forth a prima facia showing of infringement and Minerva has not raised a substantial question of invalidity with its lack of enablement argument. For these reasons, Hologic has met its burden of showing likelihood of success on the merits with respect to the '183 patent only.

25. **Irreparable harm.** Minerva's correspondence introducing Minerva EAS to physicians states that it was designed to address "difficulties with 'seating' the array, obtaining accurate width measurement, obtaining a secure cervical seal, and most importantly disappointing clinical outcomes." (D.I. 12, ex. 13) Minerva argues that "physicians are trying [Minerva EAS] because it is new technology and [has] new

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Shoketsu Kinzoku Kogyo Kabushiki Co., 344 F.3d 1359, 1366 (Fed. Cir. 2003) (A presumption of prosecution history estoppel is established by showing that the patentee made a narrowing amendment and that "the reason for that amendment was a substantial one relating to patentability.").

features." In support, Minerva offers a physician's declaration stating that he tried Minerva EAS because "it might offer . . . patients significant benefits over and above the NovaSure System." (D.I. 86 at 24; D.I. 90 at ¶ 12) Despite this argument, the description of Minerva EAS in Minerva's correspondence suffices to show "some causal nexus" between the infringing product (and certain patented features) and the alleged harm. *See Apple Inc. v. Samsung Elecs. Co.*, 809 F.3d 633, 642 (Fed. Cir. 2015) ("[T]he district court should have considered whether there is "some connection" between the patented features and the demand for Samsung's products. That is, the district court should have required Apple to show that the patented features impact consumers' decisions to purchase the accused devices.) (citations omitted); *Apple, Inc. v. Samsung Elecs. Co.*, 678 F.3d 1314, 1324 (Fed. Cir. 2012) ("If the patented feature does not drive the demand for the product, sales would be lost even if the offending feature were absent from the accused product. Thus, a likelihood of irreparable harm cannot be shown if sales would be lost regardless of the infringing conduct.").

26. **Reputation and goodwill.** Hologic offers the declarations of its sales territory manager (D.I. 14), chief operating officer (D.I. 16), and vice president of surgical sales (D.I. 19), to argue that Minerva is representing that it "invented the NovaSure system and now developed [Minerva EAS] as a 'new NovaSure' that addresses the 'weaknesses' of the existing NovaSure." Hologic alleges that these representations are confusing customers. (D.I. 11 at 16) The evidence presented in support includes an email from a Minerva sales representative that reads "the group who developed [Minerva EAS] is the same exact group who created and developed the NovaSure procedure 14 years ago." (D.I. 12, ex. 13) A template letter from a sales

representative sent to potential customers reads "Minerva was developed by the same person that invented NovaSure over 15 years ago. It is an evolutionary product that addresses many unmet needs . . . ." (D.I. 116, ex. 37 at 4746; ex. 38 at 34963; ex. 39 at 34896) The same representative tells customers that Minerva EAS was developed by the same person who invented NovaSure, as it establishes credibility and is true. (D.I. 115, ex. 27 at 106:17-107:5) Minerva responds that such correspondence is not misleading as it "displays Minerva's logos, "Minerva Surgical, Inc." signature blocks, @minervasurgical.com email addresses, and other distinctive features." (D.I. 15, exs. 13-14) Minerva offers the declaration of its vice president for sales and marketing, stating that Minerva's sales staff is instructed to compare Minerva EAS to all endometrial ablation products, not just to NovaSure. (D.I. 91 at ¶¶ 8-12) According to the record at bar, the specific representations in the evidence are true, that is, Truckai and his research group were the original inventors of NovaSure at NovaCept and have now invented Minerva EAS at Minerva. Hologic has not offered specific evidence that Minerva is representing itself as currently affiliated with Hologic or NovaSure.[15] Therefore, this fact weighs in favor of Minerva.

27. **Lost sales and price erosion.** Hologic's declarant states that several of Hologic's large customers have requested price discounts on future long-term agreements as a result of Minerva's entry into the market. (D.I. 11 at 17; D.I. 19 at ¶¶ 11-13) Minerva's sales correspondence to physicians acknowledges such discounts,[16]

[15] Hologic's declarant agreed at deposition that if Minerva sales staff "followed their script," such communications would not be misleading. (D.I. 87, ex. 35 at 139-40)
[16] For example, stating that Hologic is providing free NovaSure controllers and offering discounts in an effort to retain its customers and compete with Minerva EAS.

while encouraging physicians to try Minerva EAS. (D.I. 116, ex. 31 at 19844, ex. 32 at 2669, ex. 33 at 19444, ex. 34 at 5386) According to Hologic, it will be nearly impossible to calculate the lost downstream sales to the customers that Minerva lures away. This is due to the differing types of sales and contracts that are possible, i.e., purchasing the controller and then purchasing the disposables or receiving the controller for free and purchasing the disposables at a higher price. Hologic also asserts that price erosion will be difficult to calculate as prices are negotiated on a per customer basis. Hologic concludes that money damages will not compensate for the damage to its brand and reputation as the pioneer in endometrial ablation.[17] (D.I. 11 at 17-18) Minerva counters that Hologic has discounted NovaSure in recent years to compete with other treatments and enter into multi-product agreements, which offer discounts across product lines, but result in higher volume and increased revenue. (D.I. 86 at 22-23)

28. Sales of NovaSure were flat in the fiscal year ending in September 2012 and declined in the fiscal years ending in September 2013-2015. In its SEC filings, Hologic attributed the sales decline to lower cost alternatives and market forces.[18] (D.I. 87, exs. 30-33) There was an increase in NovaSure sales in fiscal year 2016, with Hologic reporting a $3.2 million revenue increase in NovaSure sales for the first quarter of fiscal year 2016 (October to December 2015) and NovaSure sales of $55.2 million (an increase of 8.1%) for the second quarter (January to March 2016).[19] (D.I. 87, ex. 34;

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[17] Hologic has not offered to license the patents-in-suit to a third party.
[18] Minerva also points to Hologic's unsuccessful launch of NovaSure 4.0, which failed in early 2015, as a factor in the fluctuating price for NovaSure. (D.I. 86 at 22)
[19] According to Hologic, the most recent increase was the result of the unexpected recall and exit from the market of Johnson & Johnson's competing "ThermaChoice" product, which left a sudden, large demand that both Hologic and Minerva have sought to satisfy. (D.I. 125)

D.I. 124, ex. 1) In sum, Hologic carefully tracks the average price and sales volume of NovaSure for each of its accounts, weakening Hologic's argument that money damages would not suffice. (D.I. 87, ex. 35 at 13,164-65) The court concludes that this factor is neutral.

29. **Other factors.** Hologic points out that it is in direct competition with Minerva and Minerva is focusing its efforts on Hologic's existing high volume customers. The record demonstrates that the parties compete with each other as well as with other endometrial ablation products (e.g., Johnson & Johnson's ThermaChoice and Boston Scientific's HTA), lower cost treatments and procedures (e.g., over-the-counter hormone pills and intrauterine devices ("IUDs")), and traditional surgical procedures (e.g., hysterectomies and dilation/curettage). (D.I. 86 at 21-22; D.I. 87, exs. 30-33) This factor is neutral.

30. Hologic asserts that Minerva's willful copying shows irreparable harm. Hologic bases its copying allegations on the similarity in key product features of NovaSure and Minerva EAS (D.I. 11 at 9),[20] as well as the allegations of misrepresentation by Minerva discussed above in relation to reputation and goodwill. Minerva denies the copying allegations, representing that it uses a different technology,[21] a single return electrode on the exterior of a plasma forming array to ablate tissue. The plasma forming array has a thin silicone membrane allowing thermal ablation. Minerva's technology is the result of seven years of research, with FDA trials

[20] At least two physicians noted the similarities in the technology. (D.I. 115, ex. 8; D.I. 116, ex. 66 at 32624)

[21] Minerva represented to the FDA that Minerva EAS was "almost dead identical to NovaSure except [that it uses] plasma energy (RF)." (D.I. 116, ex. 67)

and patent applications. Moreover, visual dissimilarity and branding dispel confusion. (D.I. 86 at 5-7) This factor is neutral.

31. Minerva argues that Hologic unreasonably delayed bringing the lawsuit and present motion, which should weigh against a finding of irreparable harm. Hologic had some notice and knowledge of Minerva EAS as it investigated acquiring Minerva in 2011-12 with information provided pursuant to a non-disclosure agreement. Hologic avers that the FDA approved Minerva EAS in August 2015, Hologic obtained a device in September 2015 to analyze whether there was a good faith basis for infringement, filed the present lawsuit in November 2015, and moved for the present injunction in December 2015. While Hologic's initial investigation may not have been focused on infringement, it does appear that the timing of its lawsuit and motion strategically coincides with the launch and starting sales of Minerva EAS. *Hybridtech, Inc. v. Abbott Labs.*, 849 F.2d 1446, 1457 (Fed. Cir. 1988) ("A period of delay is but one circumstance that the district court must consider in the context of the totality of the circumstances."). This factor is neutral.

32. **Irreparable harm – conclusion.** Based on the arguments presented above, most of the factors presented to the court are neutral. Therefore, Hologic has not demonstrated irreparable harm due to competition from Minerva.

33. **Balance of harms.** This factor is largely neutral. Hologic alleges that it has invested heavily in making NovaSure the leading treatment in endometrial ablation through additional clinical work and research, training and education for physicians, and training a salesforce. The court has determined that Hologic may be adequately compensated by money damages. Although Minerva took a calculated risk launching

its product, an injunction precluding Minerva from selling its only product would cause it great harm.

34. **Public interest.** This factor is largely neutral. Although the public has an interest in protecting valid patents, patients have an interest in new developments in medical technologies. Each party holds up data and argument regarding "safety and efficacy" for the court to consider in the present analysis. The FDA has approved Minerva EAS and any analysis of the safety and efficacy thereof is outside the purview of the court in the present context.

35. **Conclusion.** For the foregoing reasons, Hologic's motion for preliminary injunction (D.I. 9) is denied.

United States District Judge